

INFORMATION FILED: 6-5-57, Dist. Mass., against Edward L. Doolan, t/a Raleigh Drug Co., Springfield, Mass., and Robert J. O'Neil (pharmacist).

CHARGE: Between 5-8-56 and 6-14-56, *Dexedrine Spansule capsules* (counts 1 and 7), *Gantrisin tablets* (counts 2 and 5), *secobarbital sodium capsules* (counts 3 and 6), and *Butazolidin tablets* (counts 4 and 8) were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Doolan to all counts of information and by O'Neil to counts 1, 3, 4, 5, and 8.

DISPOSITION: 10-7-57. Doolan fined \$1,000 and O'Neil \$200.

5426. (F.D.C. No. 40442. S. Nos. 62-462 M, 62-465 M, 62-480 M, 63-293 M.)

INFORMATION FILED: 10-3-57, E. Dist. N. Y., against Pincus Goldman, Brooklyn, N.Y.

CHARGE: Between 2-5-57 and 3-7-57, *Gantrisin tablets* and *Dexedrine Sulfate tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber, and *AM Plus capsules* and *Banthine tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11-5-57. \$400 fine.

5427. (F.D.C. No. 40425. S. Nos. 43-447/8 M, 44-526/7 M.)

INFORMATION FILED: 7-5-57, W. Dist. Ky., against Herschel G. Compton, t/a Rogers Rexall Drug Store, Barlow, Ky.

CHARGE: Between 3-22-57 and 3-29-57, *thyroid tablets*, *Dexedrine Sulfate tablets*, *Equanil tablets*, and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10-29-57. \$200 fine.

5428. (F.D.C. No. 35147. S. Nos. 2-527 L, 2-530 L, 2-548 L, 59-621 L, 59-624/5 L.)

INFORMATION FILED: 1-6-54, S. Dist. Fla., against Rutherford T. Carlisle, t/a Carlisle Drugs, Jacksonville, Fla.

CHARGE: Between 12-8-52 and 2-16-53, *dextro-amphetamine sulfate tablets* were dispensed twice (counts 1 and 2) and *thyroid tablets* were dispensed once (count 3) without a prescription, and *secobarbital sodium capsules* were dispensed twice (counts 4 and 5) and *pentobarbital sodium capsules* were dispensed once (count 6) upon request for a prescription refill without authorization by the prescriber.

DISPOSITION: On 1-27-54, the defendant entered a plea of not guilty. Thereafter, he filed a motion for discovery and inspection, a motion for return of seized property and suppression of evidence, a motion for bill of particulars, and a motion to dismiss. On 8-4-55, the court denied the motion for return of seized property and suppression of evidence; granted the motion for discovery, in part; granted the motion for bill of particulars, in part; and denied the motion to dismiss as to counts 1 through 3, and granted the motion to dismiss as to counts 4, 5, and 6, thereby dismissing those counts.

The defendant filed a motion for rehearing; and the Government filed a motion for rehearing and a motion for order clarifying the basis for the

dismissal of counts 4, 5, and 6. On 9-2-55, the court denied all three motions.

The Government appealed the dismissal of counts 4, 5, and 6 to the United States Court of Appeals for the Fifth Circuit. On 5-31-56, the court of appeals handed down the following opinion (234 F. 2d. 196):

HUTCHESON, Chief Judge: "The appeal is taken pursuant to 18 U.S.C. 3731, from a final order dismissing Counts IV,¹ V and VI of a six count criminal information instituted under the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

"Each of the three counts involved charges a separate violation of 21 U.S.C. 331(k). Each count charges that on different occasions the defendant caused an act to be done with respect to a drug while it was being held for sale after shipment in interstate commerce, in effect refilling a prescription without the authorization of its prescriber, as required by 21 U.S.C. Sec. 353(b)(1), which resulted in the drugs being misbranded.

"In Count IV there is involved the drug secobarbital sodium or seconal, and in Counts V and VI the drug sodium pentobarbital. The information alleges both of these drugs to be within the class of drugs described in 21 U.S.C. 353(b)(1)(A), i.e., a habit-forming drug to which 21 U.S.C. 352(d) applies.

"The defendant moved to dismiss the information citing thirteen grounds therefor, including alleged defects in both the information and the statute.

"On August 4, 1955, the district court denying defendant's motion as to Counts I, II, and III, granted it as to, and ordered dismissal of, Counts IV, V, and VI.

"Appealing from the order of dismissal, the United States is here insisting that each of the dismissed counts states facts sufficiently charging an offense in that each count specifically and clearly charges that the act of dispensing

¹"COUNT IV—

"The United States Attorney further charges:

"That prior to Feb. 16, 1953, a number of secobarbital sodium capsules, a drug within the meaning of 21 U.S.C. 353(b)(1)(A) as amended, were shipped in interstate commerce into the State of Florida, in a bottle labeled in part as follows:

Caution—Federal law prohibits
dispensing without prescription.

"That thereafter, on or about Feb. 16, 1953, and while a number of capsules of said drug were being held for sale after shipment in interstate commerce, as aforesaid, at Carlisle Drugs, 5012 West Beaver Street, Jacksonville, Florida, the said Rutherford T. Carlisle, an individual, at the times hereinbefore mentioned trading and doing business as Carlisle Drugs, the defendant herein, did, at Jacksonville, Florida, within the Southern District of Florida, cause a number of capsules of said drug to be dispensed in a vial to one Hosea R. Wallace, upon his request for a refill of a written prescription identified as number 8683, issued on or about Feb. 11, 1953, without obtaining authorization by the prescriber;

"That displayed upon said vial was certain labeling which consisted among other things, of the following printed and graphic matter:

Carlisle Drugs
5012 W. Beaver St. Jacksonville, Florida
No. 8683 Dr. Grizzard
George R. Fowler
One only at bed time
2.13.53

"That said act of causing the dispensing of said drug as aforesaid was an act caused to be done by said defendant, contrary to the provisions of 21 U.S.C. 353(b)(1), which resulted in said drug in said vial being misbranded while held for sale, in violation of Title 21, U.S. Code, Sec. 331(k)."
Count V is identical with Count IV except as to the drug, the person to whom dispensed and the date of dispensing, while Count VI is identical with Count V except as to the date of dispensing.

as alleged was prohibited by 21 U.S.C. 353(b)(1),² and in violation of 21 U.S.C. 331(k),³ for which sec. 333,⁴ 21 U.S.C. prescribes the penalty.

"In support of this position, it points out that the last sentence of 21 U.S.C., 353(b)(1), recited in each of the dismissed counts, provides that the act of dispensing a drug contrary to the provisions of this paragraph *'shall be deemed to be an act which results in the drug being misbranded while held for sale,'* [Emphasis supplied], an act prohibited by Sec. 331(k) which prohibits *'the alteration, mutilation * * * or the doing of any other act with respect to a food, drug * * * while such article is held for sale* (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.' [Emphasis supplied.]

"Appellee agrees that Counts IV, V, and VI charge the appellee with refilling a written prescription without obtaining the authorization of the prescriber, that each count charges that the barbiturate in question is a drug within the meaning of 21 U.S.C. 353(b)(1) and that each count then goes on to allege that the act of dispensing the drug was an act done by the appellee contrary to the provisions of 21 U.S.C. 353(b)(1), 'which resulted in said drug in said box being misbranded while held for sale in violation of 21 U.S.C. 331(k).'

"He argues that each of the counts are duplicitious in that they charge two offenses, (1) dispensing drugs without a prescription and (2) that the drug was misbranded in violation of another section.

"In addition, without clearly pointing out why that would make them so, appellee insists that Sections 353(b)(1) and 331(k) are unconstitutional in that they purport to affix a meaning and give a content to the word, 'misbranded' quite the contrary to the meaning given it in Webster's Dictionary and the federal cases, to-wit: 'to brand falsely; specifically, to brand as containers of drugs or food stuffs in contravention of statutory requirements.' So insisting and citing in support *U.S. v. Cargill*, 334 U.S. 174, and *Connally v. General Construction*, 269 U.S. 385, appellee urges upon us that the sales of the barbiturates did not and could not amount to 'alteration, mutilation, destruction, obliteration, or removal of the whole or any part of labelling;' as defined in Sec. 331(k); that the appellant must, therefore, contend that the offense is charged in that part of the section which provides, 'or the doing of any other act with respect to food, drugs, * * * which results in such article being adulterated or misbranded,' and that this produces a contradiction and vagueness which deprives the defendant of due process in failing to give him notice of the offense with which he is charged.

"We do not regard these positions as well taken. Giving the fullest effect possible to appellee's objections, they come at last to no more than this, that it is an unduly awkward way to go about charging an offense to have to rely upon three separated sections to make it out. While at first blush this seems to be so, upon analysis and understanding it clearly enough appears: that, as to drugs of the habit forming group, congress has prohibited the refilling of a prescription therefor without authorization of the issuing physi-

² 21 U.S.C. 353(b)(1)

"A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) applies; or

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

³ 21 U.S.C. 331(k)

"The following acts and the causing thereof are hereby prohibited:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

⁴ 21 U.S.C. 333. Penalties—Violation of Sec. 331.

"(a) Any person who violates any of the provisions of Sec. 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1000, or both such imprisonment and fine; * * *"

cian; and that, instead of fixing the penalty for this act by directly setting it out in the section carrying the prohibition, it has declared the act of so refilling to be the same as misbranding and subject to the same penalty.

"It did this by setting out in 353(b) (1) the only way in which drugs of the kind dealt with can be dispensed, and then in the same section going on to say that the act of dispensing such a drug, contrary to the provisions of the paragraph, shall be deemed to be an act which results in the drug being misbranded. This established, by law in this section, there is required only resort to 21 U.S.C. 331(k), which denounces the offense of misbranding, and to Sec. 333, which fixes the penalty for that offense. When this resort is had, the conclusion is inescapable, we think, that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353(b) (1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding.⁵ This necessarily results from the use in Sec. 353(b) (1) of the language, 'the act shall be deemed to be an act which results in the drug being misbranded while held for sale.'

"In *Bowers v. United States*, 226 F.(2) 424, this court dealt with a statute using substantially the same language. We there pointed out, one judge dissenting, that a statute using the words 'deemed to have been marketed in excess of the quota' was intended to operate not as a presumption of fact but as a statement of a substantive rule of law, the meaning, purpose and effect of which was that the same penalty should be imposed for the failure of the producer to account for the disposition of any peanuts as was provided for, and imposed upon, excess marketing. As we held there, we hold here, that the use of the word 'deemed' in the act creates an irrebuttable presumption, a rule of substantive law, and that the doing of the prohibited act, dispensing the drugs contrary to the provision of Sec. 353(b) (1) and without the authorization of the prescriber, makes refilling misbranding and subjects the dispenser to the penalties provided for misbranding.

"It was error to dismiss the three counts. The order is REVERSED and the cause is REMANDED for further and not inconsistent proceedings.

"CAMERON, *Circuit Judge*: 'I concur in the result.' "

The defendant petitioned for rehearing, which was denied on 6-30-56. A petition for a writ of certiorari was filed with the United States Supreme Court by the defendant; the court denied the petition (352 U.S. 841).

On 4-15-57, the defendant entered a plea of guilty to counts 4, 5, and 6 of the information, and the charges on counts 1, 2, and 3 were dismissed by the Government. On 4-26-57, the court fined the defendant \$100.

5429. (F.D.C. No. 39191. S. Nos. 58-810/12 M.)

INFORMATION FILED: 6-15-56, Dist. Colo., against Edith Lillian Every, also known as Mrs. H. R. Marshall, Denver, Colo.

CHARGE: Between 5-18-56 and 5-31-56, *dextro-amphetamine sulfate tablets* were dispensed twice (counts 1 and 3) and *pentobarbital sodium capsules* were dispensed once (count 2) without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial on 10-15-56. On 10-16-56, the court dismissed counts 1 and 3 on the basis that the evidence presented by the Government was insufficient to establish that dextro-amphetamine sulfate is a drug within the meaning of Section 503(b) (1) (B). On 10-17-56, the jury found the defendant guilty as to count 2.

The defendant, on 11-2-56, made a motion for acquittal and a motion for a new trial, based upon the contention that a photostatic copy of a letter that had been introduced into evidence at the trial was (a) not the best evidence

⁵ *United States v. Debrow*, 346 U.S. 374; *United States v. Sullivan*, 332 U.S. 689; *United States v. Arnold's Pharmacy*, 116 Fed. Supp. 370; *Jordan v. DeGeorge*, 341 U.S. 223; *Boyce Motor Lines v. United States*, 342 U.S. 337.